

REMARKS

By the above amendment, Claims 1-20 have been cancelled without prejudice or disclaimer. New Claims 21-45 have been added.

Restriction Requirement

Applicants hereby elect, with traverse, to prosecute Group II, which includes and is drawn to new Claims 24-29 and 32-33, which correspond to original Claims 3-6 and 9-13. Further, Applicants elect, with traverse, to prosecute claims related to the polynucleotide sequences encoding the polypeptide sequence of SEQ ID NO:1, which sequences include SEQ ID NO:18.

Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution which were imposed in the Office Action mailed July 24, 2003 for at least the following reasons.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8<sup>th</sup> edition, published August, 2001) (hereinafter "MPEP") provides:

... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

*Id* at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

*Id* at page 1800-149, column 1.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions

of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

Unity of Invention is accepted as between claims to polypeptide sequences and claims to the polynucleotide sequences which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 (“[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...”)

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptides comprising the sequence of SEQ ID NO:1 (*i.e.*, Claims 21-23 and 37-42) and as to claims drawn to polynucleotide sequences which encode those polypeptides (*i.e.*, Claims 24-30, 32-36, and 43-45).

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 21-30 and 32-45, and examine those claims in a single application.

Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

*Id* at page 800-61.

MPEP 1893.03(d) similarly provides:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

*Id* at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all

of Applicants' claims, and which define the contribution over the prior art made by each of them. Furthermore, antibody Claim 31 is technically interrelated to the polypeptide claims since that claim recites an antibody which specifically binds, *inter alia*, a polypeptide comprising the amino acid sequence of SEQ ID NO:1. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

No Undue Burden

Furthermore, Applicants submit that the invention encompassed by the claims of Group II, (drawn to polynucleotides, expression vectors, and host cells) could be examined at the same time as the invention encompassed by the claims of Group I (polypeptides, method for production, and method for treating or preventing a disorder) and Group IV (antibodies) without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polynucleotides of Group II would reveal information regarding the novelty of the polypeptides of Group I and the antibodies of Group IV.

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement and examine all the claims in a single application.

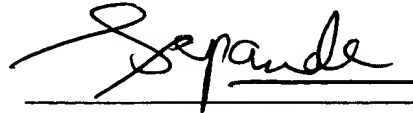
Moreover, Applicants submit that not only would there be no undue burden in examining Claims 34-36 (Group III) and Claims 43-44, but, in addition, these claims are methods of using the polynucleotides of Group II. Therefore, Claims 34-36 and 43-44 should be examined together with the polynucleotides of Group II, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Please charge Deposit Account No. **09-0108** in the amount of \$ 90.00 as set forth in the enclosed fee transmittal letter. If the USPTO determines that an additional fee is necessary, please charge any required fee to Deposit Account No. 09-0108.

Respectfully submitted,

INCYTE CORPORATION

Date: Aug. 20, 2003



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Limited Recognition (37 C.F.R. 10.9 (b)) attached

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